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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,324	03/29/2004	Heidi A. Tissenbaum	UMY-035	5837

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,324	TISSENBAUM ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1 – 48, drawn to methods of identifying agents, classified in class 435, subclass 7.21 for example.

   II. Claims 49 – 50, drawn to novel agents and pharmaceutical compositions comprising same, classification dependent upon structure.

   III. Claims 51 – 56, drawn to methods of enhancing activity by administering agents, classification dependent upon structure.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to screening methods on the one hand and products on the other. The method steps set forth in Group I are not required to make or to use the products of Group II. Furthermore the search required for the steps set forth in Group I would not be informative as to the novelty or non-obviousness of the products of Group II. Since the searches required for consideration of the screening methods are not coextensive with the searches required for the products, considering both inventions together would be burdensome.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are both methods but they require different steps and different starting materials. Group I requires a cell or an animal to be tested and does not require a subject in need of enhanced longevity, which is required for Group III. Group III requires the administration of an agent of undisclosed structure to the animal, which is not required for Group I. Search for the two inventions are not coextensive, thus consideration of the two groups together would be burdensome for the examiner.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products of Group II can be used for modulating neurotransmitter activity, i.e. for treatment of epilepsy. The products of Group II are to be identified by the methods of Group I; however since the methods of Group I encompass finding agents which modulate neurotransmitter activity, the methods would be expected to identify anti-epileptic drugs. Furthermore search for the products of undisclosed structure would not be informative as to whether those products had been administered to a subject in need of longevity enhancement.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because they require different searches which are not coextensive with one another, restriction for examination purposes as indicated is proper.

Requirement for Further Restriction Within Group I

4. Group I encompasses methods of identifying agents which modulate several neurotransmitter signaling pathways. The pathways are:

a) cholinergic pathway

b) serotonergic pathway

c) GABA pathway

The methods of identifying agents which modulate each of these pathways are distinct and independent. Each method requires different starting materials, namely the various components of the signaling pathway. Steps for identifying agents which modulate a cholinergic pathway cannot be substituted for the steps that identify agents which modulate a GABA pathway. Additionally, agents identified as agonists of a GABA pathway would not be expected to be useful in the same way that agonists of a cholinergic pathway are, for example. GABA agonists are inhibitory, whereas cholinergic agonists are excitatory. Thus the methods for identifying agents which modulate the various pathways are patentably distinct. Additionally, consideration of each method requires search for the appropriate neurotransmitter signaling pathway. Search for a cholinergic or serotonergic pathway would not be expected to turn up relevant information on a GABAergic pathway. So consideration of more than one neurotransmitter signaling pathway would be burdensome for the examiner.

Thus if applicant elects Group I for prosecution on the merits, applicant must further elect a single neurotransmitter signaling pathway to which prosecution will be restricted. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Requirements for Elections of Species Within Group I

5. This application contains claims directed to the following patentably distinct species:

Specific signaling pathway molecules

a) muscarinic receptor

b) EGL-30

c) EGL-8

d) serotonin receptor

e) CAT-1

f) GOA-1

g) DGK-1

h) UNC-13

i) PKC

j) UNC-18

k) UNC-64

l) SNAP-25

m) synaptobrevin

n) UNC-31

Specific insulin signaling pathway molecules

o) DAF-2

p) AAP-1

q) IRS

r) AGE-1

s) PDK-1

t) AKT-1

u) AKT-2

v) DAF-18

The species are independent or distinct because in the case of the signaling pathway molecules, each named molecule is patentably distinct, biochemically unique, shares no common structure with others that imparts a shared utility, and cannot be substituted one for the other.

Applicant must elect a single member from each of the two sets of species above in response to this requirement.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 – 3, 5, 7, 10 – 56 are generic with respect to signaling pathway molecules.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DK

Daniel E. Kolker, Ph.D.
July 7, 2006

RCH

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER